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## **REMARKS**

In this Amendment, claims 1-29, 35 and 46 are canceled without prejudice or disclaimer. Claims 30-34, 36-44 and 47 are amended and claims 48-64 are newly presented. Claim 45 was previously presented. It is submitted that no new matter has been added by virtue of the amended claims and the new claims, which are supported by the claims and the disclosure of the application as originally filed.

More specifically, claims 30-34, 36-44 and 47 have been amended to remove non-standard claim language. Accordingly, new dependent claims 48-64 have been added, based on the clerical amendments made to the aforementioned claims.

The currently pending claims are now claims 30-34, 36-45, and 47-64.

The Examiner objected to the disclosure of the specification as containing an informality in the heading before the claims. Applicants have reviewed the specification as originally filed and find that on page 33 of the original specification, the heading reads "<u>CLAIMS</u>". In this Amendment, the term "<u>CLAIMS</u>" has been replaced with , "<u>WHAT IS CLAIMED IS:</u>", which Applicants respectfully submit is an acceptable heading for the claims portion of the instant application. Accordingly, it is respectfully requested that this objection be withdrawn.

## The claims fulfill the requirements of 35 U.S.C. §112, second paragraph

Claims 31, 33, 34 and 36-46 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Examiner states that there is an alleged lack of clarity regarding claim 31(c) and that the term "especially" renders claims 33 and 38 indefinite. It is submitted that presently amended claims moot this rejection. Support for the amendment to claim 31(c) is found in the instant specification, *inter alia*, on page 25, lines 7-10. Withdrawal of this rejection is thus respectfully requested.

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## **Double Patenting**

Claims 30-32, 34, 46 and 47 were provisionally rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 29-34, 36-41, 46 and 47 of co-pending application U.S. Serial No. 10/461,393 (hereinafter "the '393 application"). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

It is respectfully submitted that claims 30-32, 34, 46 and 47 of the instant application are not drawn to "pharmaceutically acceptable starch with limitations that are also seen in claims 29-34, 36-41, 46 and 47 of the '393 application", as stated in the Office Action (page 3). The claims of the instant application are directed to a pharmaceutically acceptable starch and microparticles based on said starch, in which the characteristics of the starch are different from those of claims 29-34, 36-41, 46 and 47 of co-pending '393 application. More specifically, while claims 30-32, 34, 46 and 47 of the instant application are directed to a starch in which the molecular weight of amylopectin is reduced by shearing, the claims of the '393 application are directed to a starch in which the molecular weight of amylopectin is specifically reduced by acid hydrolysis. In accordance with the present invention, shearing allows a desired molecular weight distribution of the starch to be obtained. (See, for example, the instant specification on page 18, lines 14-16 and lines 23-32).

In view of the above, Applicants submit that the present claims are not directed to the same invention as the relevant claims of the '393 application. Withdrawal of the 35 U.S.C. §101 rejection is thus respectfully requested.

Claims 30, 31, 36 and 42-45 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 and 17-19 of U.S. Patent No. 6,692,770 ("the '770 patent"). According to the Examiner, the conflicting claims are not identical, but are considered not patentably distinct from each other.

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Applicants submit herewith a terminal disclaimer, statement pursuant to 37 C.F.R. §3.73(b) and the fee required pursuant to 37 C.F.R. §1.20(d) to overcome the rejection under the judicially created doctrine of obviousness-type double patenting in view of the '770 patent claims.

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## **CONCLUSION**

Applicants respectfully submit that the present application is now in condition for allowance. An action progressing this application to issue is courteously urged.

Should any additional fees be deemed to be properly assessable in this application for the timely consideration of this Amendment, or during the pendancy of this application, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. 50-0311; Reference No. 28069-585 DIV; Customer No. 35437. Should an extension of time further to that requested herein be required in this application, the Commissioner is hereby requested to grant a petition for an extension of time such as may be required, and to change any fee(s) related thereto, to the aforementioned Deposit Account No., Reference No. and Customer No.

If the Examiner believes that further discussion of the application would be helpful, he is respectfully requested to telephone the Applicants' undersigned representative at (212) 692-6742 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

Respectfully submitted,

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Date: December 13, 2004

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